



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Roger P. Jackson

Serial No.: 09/644,777

Date: December 9, 2008

Filed: August 23, 2000

Group Art Unit: 3732

Exam: Cris Loiren Rodriguez

For: THREADFORM FOR MEDICAL IMPLANT CLOSURE

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Kansas City, Missouri

Appeal No. _____

Mail Stop Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

ATTENTION: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF

This brief is filed in support of the Notice of Appeal in this application which was mailed on May 27, 2008. It is noted that the date for response was reset to be one month from the Pre-Appeal Brief Review dated August 11, 2008.

The fees required under 41.2(b)(2) are submitted herewith.

I REAL PARTY IN INTEREST

The applicant Roger P. Jackson is the real party in interest.

II RELATED APPEALS AND INTERFERENCES

There are no current related appeals or interferences.

III STATUS OF CLAIMS

The status of the claims in this application are:

A. TOTAL NUMBER OF CLAIMS IN APPLICATION: 27

B. STATUS OF ALL OF THE CLAIMS:

1. Claims canceled: 8, 27-49
2. Claims withdrawn from consideration but not canceled:
None
3. Claims pending: 1-7, 9-26, 50 and 51
4. Claims allowed: None
5. Claims rejected: 1-7, 9-26, 50 and 51

C. CLAIMS ON APPEAL: 1-7, 9-26, 50 and 51

IV STATUS OF AMENDMENTS

No amendments are pending.

V SUMMARY OF CLAIMED SUBJECT MATTER

CONCISE EXPLANATION OF INDEPENDENT CLAIM 1

Claim 1 calls for a medical device comprising a first implant 7 (page 9, line 13 to page 10, line 10), shown in Fig. 2 having spaced arms 17 and 18 (page 9, line 22 to page 10, line 4), a head 14 (page 9, line 22) with a channel 20 (page 10, line 2) and a second implant (closure) 5 (page 10, line 18 to page 11, line 5), shown best in Figs. 3 and 4. The second implant 5 includes a thread 1 (page 11, line 19 to page 14, line 6) that has a leading surface 40 and trailing surface 41 (both at page 11, line 23 to page 12, line 8). The leading surface 40 has an inner edge 44 and an outer edge 45 (both at page 12, lines 6 to 7). The trailing surface 41 has an inner edge 48 and an outer edge 49 (both at page 12, lines 7 to 8). Intersections of a plane passing through an axis of rotation A (page 12, line 23 to page 14, line 6) with both the leading surface 40 and trailing surface 41 slope rearwardly relative to advancement of the closure 5 (page 13, line 7 to page 14, line 6). The arms 17 and

18 include a thread 53 (page 14, lines 7 to 14) that mates with the thread 1.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 13

Claim 13 calls for a medical implant 7 (page 9, line 13 to page 10, line 10), shown in Fig. 2 having spaced arms 17 and 18 (page 9, line 22 to page 10, line 4) and a closure 5 (page 10, line 18 to page 11, line 5), shown best in Figs. 3 and 4, located between the arms 17 and 18. The closure 5 includes a thread 1 (page 11, line 19 to page 14, line 6) that has a leading surface 40 and trailing surface 41 (both at page 11, line 23 to page 12, line 8). The leading surface 40 has an inner edge 44 and an outer edge 45 (both at page 12, lines 6 to 7). The trailing surface 41 has an inner edge 48 and an outer edge 49 (both at page 12, lines 7 to 8). Intersections of a plane passing through an axis of rotation A (page 12, line 23 to page 14, line 6) with both the leading surface 40 and trailing surface 41 slope rearwardly relative to advancement of the closure 5 (page 13, line 7 to page 14, line 6), see Fig. 4 especially. The arms 17 and 18 include a thread 53 (page 14, lines 7 to 14) that mates with the thread 1.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 17

Claim 17 calls for a medical implant 7 (page 9, line 13 to page 10, line 10), shown in Fig. 2 having spaced arms 17 and 18 (page 9, line 22 to page 10, line 4) and a closure 5 (page 10, line 18 to page 11, line 5), shown best in Figs. 3 and 4, located between the arms 17 and 18. The closure 5 includes a thread 1 (page 11, line 19 to page 14, line 6) that has a leading surface 40 and trailing surface 41 (both at page 11, line 23 to page 12, line 8) that mates with a mating thread 53 (page 14, lines 7 to 14) on the arms 17 and 18. The leading surface 40 has an inner edge 44 and an outer edge 45 (both at page 12, lines 6 to 7). The trailing surface 41 has an inner edge 48 and an outer edge 49 (both at page 12, lines 7 to 8). The inner edge 48 having a generally constant radius over the length of the thread 1.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 18

Claim 18 calls for a medical implant (closure) 5 (page 10, line 18 to page 11, line 5), shown best in Figs. 3 and 4 for closing between a pair of spaced arms 17 and 18 (page 9, line 22 to page 10, line 4) of a head 14 (page 9, line 13 to page 10, line 10), shown in Fig. 2. The closure 5 includes a thread 1 (page 11, line 19 to page 14, line 6) that has a leading surface 40 and trailing surface 41 (both at page 11, line 23 to page 12,

line 8). The leading surface 40 has an inner edge 44 and an outer edge 45 (both at page 12, lines 6 to 7). The trailing surface 41 has an inner edge 48 and an outer edge 49 (both at page 12, lines 7 to 8). Intersections of a plane passing through an axis of rotation A (page 12, line 23 to page 14, line 6) with both the leading surface 40 and trailing surface 41 slope rearwardly from the inner edges 44 to outer edges 45 over substantially the entire length of the trailing surface 41.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 19

Claim 19 calls for a medical implant 7 (page 9, line 13 to page 10, line 10), shown in Fig. 2 having spaced arms 17 and 18 (page 9, line 22 to page 10, line 4) and a closure 5 (page 10, line 18 to page 11, line 5), shown best in Figs. 3 and 4. The closure 5 includes a thread 1 (page 11, line 19 to page 14, line 6) that has a leading surface 40 and trailing surface 41 (both at page 11, line 23 to page 12, line 8) that is received in a mating thread 53 (page 14, lines 7 to 14). The leading surface 40 has an inner edge 44 and an outer edge 45 (both at page 12, lines 6 to 7). The trailing surface 41 has an inner edge 48 and an outer edge 49 (both at page 12, lines 7 to 8). The trailing surface 41 sloping rearwardly from the inner edge 48 to the outer edge 49. The trailing surface inner edge 48 being spaced from the leading

surface inner edge 44 and the trailing surface outer edge 49 being in close proximity to the leading surface outer edge 45 such that the thread 1 has a generally triangular cross-section.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 21

Claim 21 calls for a medical implant (closure) 5 (page 10, line 18 to page 11, line 5), shown best in Figs. 3 and 4 that is sized and shaped to be threadedly received between a pair of spaced arms 17 and 18 (page 9, line 22 to page 10, line 4) of a head 14 (page 9, line 13 to page 10, line 10), shown in Fig. 2. The closure 5 having a cylindrical outer surface 32 (page 10, line 20) with a thread 1 (page 11, line 19 to page 14, line 6) thereon that has a leading surface 40 and trailing surface 41 (both at page 11, line 23 to page 12, line 8). The leading surface 40 has an inner edge 44 and an outer edge 45 (both at page 12, lines 6 to 7). The trailing surface 41 has an inner edge 48 and an outer edge 49 (both at page 12, lines 7 to 8). The trailing and leading surfaces 41 and 40 sloping rearwardly and the inner edges of each 48 and 44 respectively being spaced so the thread 1 has a generally triangular cross-section.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 22

Claim 22 calls for a medical implant 7 (page 9, line 13 to

page 10, line 10), shown in Fig. 2 with a head 14 (page 9, line 22) having spaced arms 17 and 18 (page 9, line 22 to page 10, line 4) and a closure 5 (page 10, line 18 to page 11, line 5), shown best in Figs. 3 and 4. The closure 5 includes a thread 1 (page 11, line 19 to page 14, line 6) that has a leading surface 40 and trailing surface 41 (both at page 11, line 23 to page 12, line 8). Intersections of the leading surface 40 and trailing surface 41 with a plane passing through the axis of rotation A slope rearwardly. A first angle B (page 13, line 7 to page 14, line 6) between the leading surface 40 and a line perpendicular to the axis of rotation A is substantially greater than a second angle C (page 13, line 7 to line 14) between the trailing surface 41 intersection with a line perpendicular to the axis A.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 26

Claim 26 calls for a medical implant 7 (page 9, line 13 to page 10, line 10), shown in Fig. 2 having spaced arms 17 and 18 (page 9, line 22 to page 10, line 4) and a closure 5 (page 10, line 18 to page 11, line 5), shown best in Figs. 3 and 4. The closure 5 includes a thread 1 (page 11, line 19 to page 14, line 6) that has a leading surface 40 and non parallel trailing surface 41 (both at page 11, line 23 to page 12, line 8). The leading surface 40 has an inner edge 44 and an outer edge 45

(both at page 12, lines 6 to 7). The trailing surface 41 has an inner edge 48 and an outer edge 49 (both at page 12, lines 7 to 8). An intersection of a plane with the trailing surface 41 slopes rearwardly from the trailing surface inner edge 44 to the outer edge 45.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 50

Claim 50 calls for a medical implant (closure) 5 (page 10, line 18 to page 11, line 5), shown best in Figs. 3 and 4 for closing between a pair of spaced arms 17 and 18 (page 9, line 22 to page 10, line 4) of a head 14 (page 9, line 13 to page 10, line 10), shown in Fig. 2. The closure 5 includes a threadform 1 (page 11, line 19 to page 14, line 6) that has a leading surface 40 and trailing surface 41 (both at page 11, line 23 to page 12, line 8). The leading surface 40 has an inner edge 44 and an outer edge 45 (both at page 12, lines 6 to 7). The trailing surface 41 has an inner edge 48 and an outer edge 49 (both at page 12, lines 7 to 8). Intersections of a plane passing through an axis of rotation A (page 12, line 23 to page 14, line 6) with both the leading surface 40 and trailing surface 41 slope rearwardly from the inner edge 44 to the outer edge 45 relative to the direction of advancement from respective inner edges 44 to outer edges 45 thereof.

CONCISE EXPLANATION OF INDEPENDENT CLAIM 51

Claim 51 calls for method of resisting splaying in a medical implant 7 (page 9, line 13 to page 10, line 10), shown in Fig. 2 having spaced arms 17 and 18 (page 9, line 22 to page 10, line 4) that receive a rod 6 (page 9, lines 13 to 17 and Fig. 2) by inserting a closure 5 (page 10, line 18 to page 11, line 5), shown best in Figs. 3 and 4 between arms 17 and 18. The closure 5 includes a reverse angle thread 1 (page 11, line 19 to page 14, line 6) that has a leading surface 40 and trailing surface 41 (both at page 11, line 23 to page 12, line 8) and the arms 17 and 18 have a mating thread 53 (page 14, lines 7 to 14).

VI GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Are Claims 1 to 7, 9 to 10, 12 to 26 and 50 to 51 properly rejected under 35 U.S.C. 102(e) as being anticipated by Morrison, et al. (USPN 6,296,642) and more specifically, should the Declarations of applicant claiming prior invention relative to the effective date of the Morrison, et al. patent be found to be sufficient to overcome the application of the Morrison, et al. patent?

Is Claim 11 obvious under 35 U.S.C. 103 in view of a combination of Morrison, et al. and Reed (USPN 5,499,892)?

VII ARGUMENT-REJECTIONS UNDER 35 U.S.C. 102 and 103

Applicant acknowledges that the invention shown in Morrison, et al. essentially shows and describes the invention called for in Claims 1 to 7, 9 to 10, 12 to 26 and 50 to 51 of the present application.

Applicant believes that the invention shown in the Morrison, et al. patent was most likely due to applicant's prior invention that was shown to Morrison's assignee. Although applicant did not disclose the invention directly to Morrison, the applicant's invention was disclosed to engineers who were employed by Morrison's employer and/or at least one of its subsidiaries who were stationed for approximately two years in applicant's medical offices to work on an implant line being co-developed by applicant and the Morrison assignee and/or a subsidiary thereof.

The effective date of Morrison, et al. is November 9, 1998. Applicant's application was filed on August 23, 2000 before Morrison, et al. published or issued as a patent. Therefore, Morrison is a 102(e) reference. It is urged that applicant conceived of the disclosed and claimed subject matter of his application and reduced it to practice prior to the effective date of Morrison, et al., that is prior to November 9, 1998, in the United States. Further, it is also urged that the invention was reduced to practice with due diligence in conjunction with or

in the alternative to being reduced to practice prior to the effective date of Morrison.

To support applicant's position, applicant has submitted three Declarations dated February 25, 2003; February 23, 2006 and March 12, 2007 which are attached hereto as exhibits outlining applicant's conception and reduction to practice. Where possible applicant has submitted supporting documents and pictures of prototypes; however, applicant suffered a catastrophic fire that burnt his entire house and destroyed some records and prototypes that were located there at the time of the fire. Although it is believed that the current record completely supports conception and timely reduction to practice in the U.S. prior to Morrison, et al.'s effective date, applicant would like to be able to submit additional proof that existed at one time, but cannot do so due to the loss and it is urged that the fire satisfactorily explains the lack of additional information and prototypes under Rule 131(b).

The Office action of December 26, 2007 states in general that:

"The evidence is insufficient to establish redirection to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Morrison reference. The evidence submitted with the Declaration is insufficient to establish a reduction to

practice prior to the effective filing date of the Morrison reference. - - -. The Declaration provides some evidence to support conception of the invention prior to the effective filing date of the Morrison reference; however, there is insufficient evidence provided that supports a reduction to practice prior to the effective filing date of the Morrison reference. As such, there is insufficient evidence to establish that the present invention was invented prior to the Morrison filing date."

It appears from this statement that the Office acknowledges that applicant's invention was conceived of, but does not find that it was reduced to practice prior to the effective date of Morrison, et al. While the statement repeats a number of times that the evidence is insufficient to support reduction to practice, there is no reason given as to why it is insufficient.

Applicant believes that the three above noted Declarations do support conception and reduction to practice before the effective date of Morrison, et al. It is believed that the Declarations must speak for themselves; however, the following is believed to be a relevant summary.

Applicant conceived of the invention before or during a trip to Germany from which he returned on May 17, 1991 and thereafter reduced the invention to a drawing that is of record. Applicant

attempted to have a machine shop that prepares prototypes for applicant manufacture a prototype in 1995; however, the tool and die technology available in 1995 was unable to make the undercut required on such a small device (the closures are about the size of or smaller than a pencil eraser). In the period between 1997 and 1999 the machine shop made various attempts to make prototypes. Some of these have been lost due to the fire mentioned; however, as indicated in the Declaration of March 12, 2007, a prototype closure has been found that was made during or prior to the Summer of 1997 and for which pictures (see especially Exhibit 4 of the Declaration filed March 12, 2007, showing the reverse angle thread) were submitted. The prototype shown in Exhibit 4 shows the invention essentially as it is described in Claims 18, 21 and 50. A receiver that mates with the closure has not been found. The prototypes were made in North Kansas City, USA.

Consequently, it is urged that conception and reduction to practice of the invention in the United States prior to September 1, 1997 is fully supported by the evidence of record. Alternatively, if the evidence is found to be insufficient for some of the claims for failure to provide additional prototypes or the like, it is urged that failure to provide such is satisfactorily explained due to the fire at applicant's house. Further and alternatively, it is believed that applicant's

position that sufficient evidence has been submitted to support applicant's claim to reduction practice prior to Morrison, et al.'s effective date is supported by case law such as *In re Spiller*, 500 F.2nd 1170, 1177-78 (CCPA 1974) wherein the Court held that "appellants should not be required to submit facts under Rule 131 showing that they reduced to practice that which is obvious in addition to those facts offered as showing completion of the invention, for the purpose of antedating a reference" and that the purpose of the Rule 131 showing is to establish broadly the possession of the invention. Here applicant has shown possession of the key element of the closure which forms the basis for many of the claims and for which a mating receiver is obvious to one having skill in the art.

Therefore, it is urged that Claims 1 to 7, 9 to 10, 12 to 26 and 50 to 51 are allowable over Morrison, et al.

VIII ARGUMENT - REJECTION UNDER 35 U.S.C. 103

Claim 11 stands rejected as obvious in view of a combination of Morrison, et al. and Reed. As noted above, it is believed that the invention of the present application predates the effective date of Morrison, et al. and that Claim 11 should, therefore, be allowable.

IX CLAIMS APPENDIX

Claim 1 A medical implant having a head with a pair of spaced arms and an implant closure sized to be operably threadedly received between said arms; said closure having a threadform thereon that is sized and shaped to be threadedly received in a mating threadform on said arms; said closure has a direction of advancement along an axis of rotation relative to said head; said threadform comprising:

- a) a leading surface that has an inner edge and an outer edge;
- b) a trailing surface that has an inner edge and an outer edge; and wherein
- c) intersections of a plane passing through said axis of rotation with both said leading surface and said trailing surface slope rearwardly relative to the direction of advancement from the respective inner edges to the outer edges thereof.

Claim 2 The implant according to Claim 1 wherein:

- a) the intersection of said trailing surface with a plane passing through said axis of rotation is at a first angle of from about 1° to about 45° relative to a line perpendicular to said axis of

rotation.

Claim 3 The implant according to Claim 2 wherein:

a) said first angle is between about 5° and 20°.

Claim 4 The implant according to Claim 2 wherein:

a) said first angle is between about 7° and 15°.

Claim 5 The implant according to claim 2 wherein:

a) the intersection of said leading surface with a plane passing through said axis of rotation is at a second angle of from about 30° to about 75° relative to a line perpendicular to said axis of rotation.

Claim 6 The implant according to Claim 2 wherein:

a) said second angle is in the range from 40° to 50°.

Claim 7 The implant according to Claim 1 wherein:

a) said trailing and leading surfaces are nonparallel.

Claim 8 (Canceled)

Claim 9 The closure according to Claim 50 wherein:

- a) said threadform is helically wound about said cylindrical shaped body.

Claim 10 The closure according to Claim 9 wherein:

- a) said threadform is continuous.

Claim 11 The closure according to Claim 9 wherein:

- a) said threadform is in a helical pattern, but is discontinuous.

Claim 12 The closure according to Claim 50 further including:

- a) the second implant having a receiving thread on an inner surface thereof; said receiving thread being sized and shaped to matingly and threadably receive said threadform.

Claim 13 A medical device comprising:

- a) a first implant having a head with a channel sized and shaped to receive a rod member and a pair of spaced arms on opposite sides of said channel;
- b) a second closure implant for closing between said arms; said closure implant having an axis of rotation and a thread on an outer surface thereof;

said thread being in a helical pattern on said closure implant and having a leading surface and a trailing surface; said leading surface having inner and outer edges and said trailing surface having inner and outer edges; intersections of both said leading surface and said trailing surface with a plane passing through said axis of rotation slope from respective inner to outer edges rearwardly with respect to a direction of advancement of said closure implant in closing said first implant; and

- c) each of said arms include a threadform on inner facing surfaces thereof sized and shaped to matingly and threadedly receive the thread of said closure implant.

Claim 14 The device of Claim 13 wherein:

- a) the inner and outer edges of both said leading surface and said trailing surfaces are each spaced from the axis of rotation at substantially the same radius over substantially the entire length of the thread.

Claim 15 The device of Claim 13 wherein:

- a) said inner edges of both said leading and trailing surfaces are substantially spaced and said outer edges of both said leading and trailing surfaces are in close proximity to each other throughout the length of the thread such that the thread is generally triangular in cross-section.

Claim 16 The device according to Claim 15 wherein:

- a) said cross-section has the general shape of an obtuse triangle.

Claim 17 In a medical implant having a head with a pair of spaced upright arms and a closure operably located between the arms, a thread positioned on the closure and being sized and shaped to be threadedly received in a mating thread located on the pair of upright arms; said thread having an axis of rotation with a leading surface and a trailing surface relative to advancement along the axis of rotation; the improvement comprising:

- a) said trailing surface having an inner and an outer edge; said trailing surface sloping rearwardly from the inner edge to the outer edge thereof; and said inner edge having a generally constant radius over an entire length of said thread, such that,

as said closure is advanced and applies force on a bottom side thereof, said thread resists splaying of said arms.

Claim 18 In a medical implant sized and shaped for closing between a pair of arms of a head of a bone screw and having a lower surface adapted to engage and apply pressure to a rod received in the head; said implant further having a cylindrical shaped outer surface with a thread wound in a helical pattern about said outer surface and wherein said thread has a leading surface and a trailing surface relative to advancement of the implant along an axis of rotation; the improvement comprising:

a) said trailing surface having an inner and an outer edge; any intersection of said trailing surface with a plane passing through the axis of rotation slopes rearwardly from an inner radius to an outer radius of said trailing surface over substantially the entire length of said trailing surface.

Claim 19 In a medical implant having a head with a pair of spaced arms and a closure for positioning between and closing between the arms, the closure having a thread

located thereon that is operably received in a mating thread located on said spaced arms; said thread having a leading surface and a trailing surface relative to advancement about an axis of rotation; the improvement comprising:

- a) both said leading and trailing surfaces having respective inner and outer edges; said trailing surface sloping rearwardly from the inner edge to the outer edge thereof; said trailing surface and leading surface inner edges being spaced and said trailing surface and leading surface outer edges being in close proximity to one another, such that said thread is generally triangular in cross-section.

Claim 20 The implant according to Claim 19

wherein:

- a) said cross-section is generally in the shape of an obtuse triangle.

Claim 21 In a medical implant having a

cylindrical shaped outer surface with a thread helically wound about said outer surface and wherein said implant is sized and shaped to be threadedly received between a pair of arms of a bone screw head and has a bottom surface adapted

to abut against a rod received in said head; said thread having a leading surface and a trailing surface relative to advancement of the implant along an axis of rotation and further wherein both said trailing surface and said leading surface have respective inner and outer edges; the improvement comprising:

- a) said leading and trailing surfaces both sloping rearwardly from respective inner to outer edges thereof; said trailing surface and leading surface inner edges being spaced and said trailing surface and leading surface outer edges being in close proximity to each other over substantially the entire length of the thread such that the thread has a substantially triangular shaped cross section.

Claim 22 In an orthopedic medical implant having a head with a pair of spaced arms and including a closure for operably closing between the arms, the closure having a thread thereon and the arms having a mating thread; said thread having a leading surface and a trailing surface relative to advancement about an axis of rotation; the improvement comprising wherein:

- a) both of the intersections of said leading surface

- and said trailing surface with a plane passing through the axis of rotation slope rearwardly from a radially inner edge to outer edge thereof; and
- b) a first angle between the leading surface intersection and a line perpendicular to the axis of rotation is substantially greater than a second angle between the trailing surface intersection and a line perpendicular to the axis of rotation.

Claim 23 The implant according to Claim 22 wherein:

- a) said second angle is between about 1° and 45°.

Claim 24 The implant according to Claim 23 wherein:

- a) said first angle is greater than 30°.

Claim 25 The implant according to Claim 22 wherein:

- a) said first angle is in the range from about 30° to 45° and said second angle is in the range from about 5° to 20°.

Claim 26 In a medical implant having a head with a pair of spaced arms and including a closure for closing between said arms; said closure having thereon a thread sized and shaped to be threadedly received in a mating thread on said arms;

said thread having a leading surface and a trailing surface relative to advancement about an axis of rotation; the improvement comprising:

- a) said leading surface and said trailing surface being non-parallel; and
- b) an intersection of a plane with said trailing surface slopes rearwardly from an inner edge to an outer edge of said trailing surface.

Claim 27 (Canceled)

Claim 28 (Canceled)

Claim 29 (Canceled)

Claim 30 (Canceled)

Claim 31 (Canceled)

Claim 32 (Canceled)

Claim 33 (Canceled)

Claim 34 (Canceled)

Claim 35 (Canceled)

Claim 36 (Canceled)

Claim 37 (Canceled)

Claim 38 (Canceled)

Claim 39 (Canceled)

Claim 40 (Canceled)

Claim 41 (Canceled)

Claim 42 (Canceled)

Claim 43 (Canceled)

Claim 44 (Canceled)

Claim 45 (Canceled)

Claim 46 (Canceled)

Claim 47 (Canceled)

Claim 48 (Canceled)

Claim 49 (Canceled)

Claim 50 A medical implant closure having a threadform; said closure being adapted to be threadedly receivable in a second medical implant bone screw head between spaced arms wherein said closure has a direction of advancement along an axis of rotation relative to said head; said threadform comprising:

- a) a leading surface that has an inner edge and an outer edge;
- b) a trailing surface that has an inner edge and an outer edge; and wherein
- c) intersections of a plane passing through said axis of rotation with both said leading surface and said trailing surface slope rearwardly relative to the direction of advancement from the respective inner edges to the outer edges thereof.

Claim 51 In a method of resisting arm splaying in a medical

implant having a head with a pair of spaced arms that operably receive a rod and a closure for threadedly closing between the arms; the method comprising the steps of:

- a) providing a reverse angle thread on said closure and a mating thread on said arms with said reverse angle thread aligned to urge said arms inwardly toward said closure as said closure is tightened with respect to said head; and
- b) inserting said closure between said arms and rotating said closure so as to threadedly advance said closure relative to said arms until said closure is set.

X EVIDENCE APPENDIX

- 1) DECLARATION UNDER RULE 131 dated February 25, 2003
- 2) DECLARATION UNDER RULE 131 dated February 23, 2006
- 3) DECLARATION UNDER RULE 131 dated March 12, 2007

XI RELATED PROCEEDINGS APPENDIX

NONE

Respectfully submitted,

BY: 

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P.O. Box 1450,
Alexandria, VA 22313-1540 on
December 9, 2008.

Roger P. Jackson

By 

December 9, 2008

(Date of Signature)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION UNDER RULE 131

Applicant: Roger P. Jackson

Serial No.: 09/644,777

Date: February 25, 2003

Filed: August 23, 2000

Group Art Unit: 3732

Exam: Candice Melson

For: THREADFORM FOR MEDICAL IMPLANT CLOSURE

Kansas City, Missouri

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Applicant, Roger P. Jackson, in the above captioned application for patent avers and declares as follows:

- 1) I am the inventor of the subject matter of the claims of U.S. application for patent Serial No. 09/644,777.
- 2) I am a spinal surgeon. In the late 1980's and early 1990's and especially in 1992 and 1993 I worked on developing a spinal implant system at my office in North Kansas City, Missouri which eventually became the

Liberty System of Sofamor, later Sofamor Danek, Sofamor Danek Group Incorporated, and SDGI Holdings, Inc.

- 3) During 1992 and 1993 I provided office space in my medical practice office to several engineers from Sofamor who worked as an interface between myself and Sofamor with respect to the development work I was doing. In particular, beginning in October 1992 Jean Saurat, an employee of Sofamor began work in my office and in April 1993 Paul Wisnewski, an engineer employed by Sofamor began work in my office and overlapped with Mr. Saurat.
- 4) Also especially from 1991 to 1993 (and in some cases earlier) I developed certain other inventions and concepts outside the realm of the Liberty Spinal System and disclosed these inventions and concepts to Sofamor and especially to the Sofamor engineers who were working with me on the Liberty System. I also disclosed these concepts to Dr. Hardacker in the Fall of 1992 who was a spine fellow then training in my office to practice spinal surgery.

- 5) Enclosed as Exhibit A is a drawing of a concept that I made of two closure plugs, one with a standard V thread and one with a reverse angle or buttress thread. The drawing of Exhibit A was made during a trip to Heidleberg, Germany from which I returned on May 17, 1991. The file for this drawing was created immediately upon return from this trip. During 1992 and 1993 I maintained a bound log and files on various inventions and concepts that I developed. Exhibit B is a drawing that is located in my 1992 file and was done by me in mid 1992. The bottom design in Exhibit B illustrates a reverse angle thread on a closure mechanism in accordance with my invention in the present application.
- 6) Enclosed as Exhibit C is a drawing from my bound log that was made by me and that is dated December 2, 1995. The top illustration of Exhibit C illustrates a closure plug having a reverse angle thread as disclosed and claimed in my application for patent.
- 7) The closure mechanism with the buttress and reverse angle threads that is shown in Exhibits A and B was

shared with, shown to and extensively discussed with the Jean Saurat from Sofamor and Dr. Hardacker during the period from 1992 to 1993. A letter from Dr. Hardacker dated March 19, 2001 confirms disclosure of information to him at that time and is included as Exhibit D. Dr. Hardacker was specifically shown Exhibit B and remembers this disclosure as having been shown to him and discussed in 1992. The Sofamor personnel indicated that Sofamor was not interested in the idea because Sofamor felt it was an impractical approach and they wanted to pursue a different avenue to prevent splaying of the arms of bone screw heads.

- 8) I attempted to have the device of Exhibit A constructed by Jenkins Industrial Machine Works in North Kansas City, Missouri at least as early as 1995. Jenkins is a machine shop that I use to produce many of my prototypes. The personnel at Jenkins indicated that they did not have the technology to produce the reverse angle thread on a bone screw closure mechanism at that time. The personnel at Jenkins also indicated that they had checked to see if the technology was available anywhere, but could not find the technology to build

the closure with the reverse angle thread. The personnel at Jenkins indicated that I would have to wait until the technology existed to make a prototype.

- 9) I never lost interest in the concept of using the reverse angle thread on a bone screw closure and continued to pursue making and testing a prototype.
- 10) Finally, in 1999 after much prodding, the personnel at Jenkins informed me that the technology was available to undercut the threads and manufacture a reverse angle thread on the closure mechanism. At that time, I had prototypes made and began testing the prototype. Exhibit E is a billing from Jenkins dated September 15, 1999 for the work in making a prototype. Exhibit F is another drawing of mine from my log dated March 31, 1999 showing the reverse angle thread on a closure on the left. Exhibit G is a drawing of mine dated December 2, 1995, a copy of which is located in the Jenkins files in a folder marked "Dr. Jackson". Exhibit H is another drawing from the Jackson file at Jenkins showing the reverse angle thread on a closure plug that was done by Jenkins prior to October 13, 1999

and which was labeled "Buttress" thread, as the term reverse angle thread was not in common use at that time. Exhibit I is a bill for stock used to produce a closure with a reverse angle thread from titanium stock for me that is dated October 13, 1999. Exhibits J, K and L are photographs of prototypes of the closure with the reverse angle thread made in September or October 1999. Note the device in Exhibit K has been sliced to show the cross section.

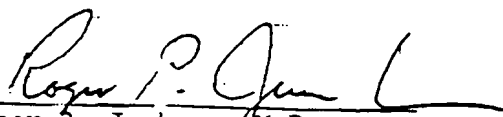
- 11) The prototypes of the closure with reverse angle threads with my invention were made by Jenkins and tested in the North Kansas City, Missouri area beginning in September and October 1999. The drawings for the present application were made from some of the first prototypes produced.
- 12) The Morrison patent 6,296,642 is assigned to SDGI Holdings, Inc. which is the holding company that owns the patents for the prior noted Sofamor company to which I disclosed my invention that is the subject matter of this application during 1992 and 1993.

13) I believe that I was the first to conceive of the idea of using a reverse angle thread on a closure plug or mechanism for an open headed bone screw, as described and claimed in my application for patent. I also believe that I reduced the concept to practice in the United States with due diligence from my date of conception in view of the slow development of the machining technology that was available to construct such a device. As the technology developed, I proceeded with the project and never lost or abandoned interest in the closure for a bone screw with the reverse angle thread. I also believe that I disclosed this invention to Sofamor which now claims to have invented the invention through its employees Morrison, et al.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may

jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,


Roger P. Jackson, M.D.

JCM:lm
PO Box 30069
Kansas City, Missouri
64112
Phone: (816) 531-3470

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, D.C. 20231 on February 25, 2003.

Roger P. Jackson
(Applicant)

By



February 26, 2003

(Date of Signature)

DAIMLERBENZ

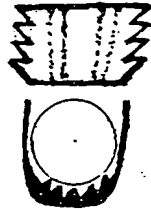
To Henri

Shumberg No. 5118

EXHIBIT

A

Plugs



Roger G. L.

Closure Mechanisms

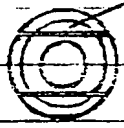


Gripping Flanges

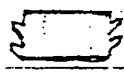


Insertion tool

Insertion tool & D.T. JCHW



Insertion tool (I. JCHW)



Gripping flanges or - JCHW

905

PROJECT Closure Mechanisms

Note' k No. _____

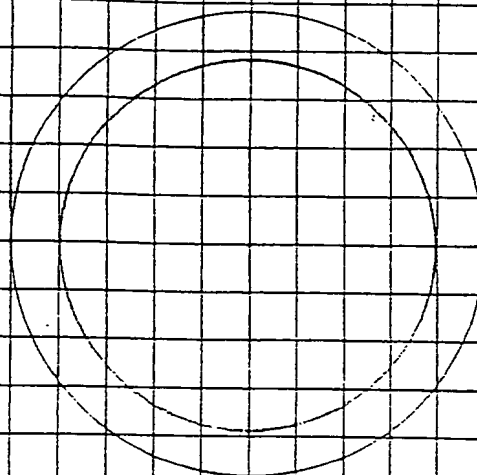
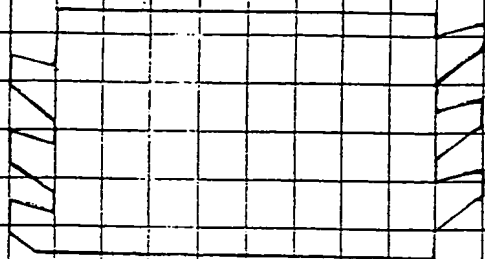
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Bumberg No. 5113

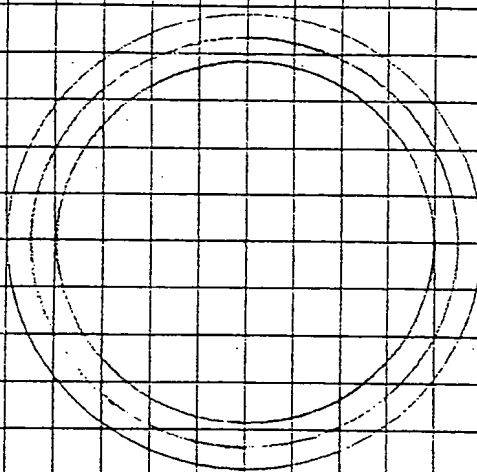
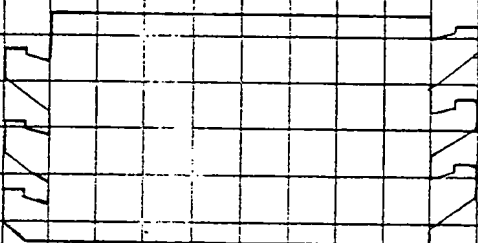
EXHIBIT

C

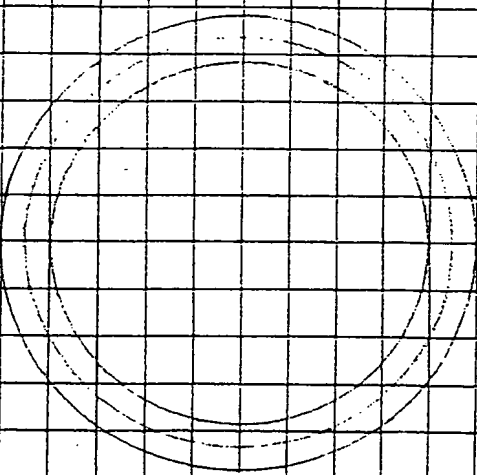
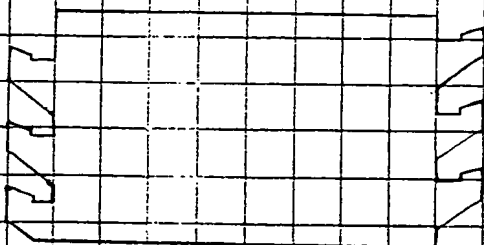
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100
100
100



Continued on Page _____

Roger [Signature]
Signed

12-2-95
Date

Read and Understood By

Chris Hob
Signed

12-9-95
Date

Medical Arts Building
1500 Albany St., Suite 905
Beech Grove, IN 46107
(317) 788-0357
Fax (317) 782-9657
1-800-428-2186
Philip W. Pryor, M.D.
James Hardacker, M.D.
Ronald A. West, PA-C

THE
SPINE
INSTITUTE



St. Vincent Carmel
Medical Pavilion
13431 Old Meridian St.
2nd Floor, Suite 200
Carmel, IN 46032
(317) 573-7733
Fax (317) 573-7739
1-800-248-4153

March 19, 2001

EXHIBIT

D

Dr. Roger Jackson
Medical Plaza North
#600
2750 Clay Edwards Dr. N.
Kansas City, Missouri 64116

Dear Roger:

I reviewed the ~~drawings of the instrumentation closure mechanisms~~ that we worked on in 1992 when I was in the Fellowship. I remember them very well. I have specific recollections and dated information of when we were working on that in ~~early September 1992 and extending through the fall of 1992~~. Having worked on this on a daily basis, and discussed this over an extended period of time, my memory and recall of this is quite extensive.

With warm regards,


JAMES W. HARDACKER, M.D.

JWH/pab



JENKINS INDUSTRIAL MACHINE WORKS, INC.

1137 SWIFT STREET
NORTH KANSAS CITY, MISSOURI 64116-4194
PHONE: 471-3785



INVOICE 27776

SOLD
TO

DR JACKSON

DATE RECEIVED 9-15-99

YOUR ORDER NO.

QUANTITY	DESCRIPTION
1	Implant — Modify Per Sketch

FREIGHT

LABOR

MAT'L

SUB-TOTAL 22,827.⁷⁹

SALES TAX 1535.¹⁷

TOTAL 24,362.⁹¹

RESALE ☐

REPAIR ☐

FABRICATION ☒

OTHER ☐

PURCHASE / REPAIR AUTHORIZATION

APPROVED:

CUSTOMER

JENKINS INDUSTRIAL MACHINE WORKS, INC.

JOB PICKED UP OR ACCEPTED BY:

DATE:

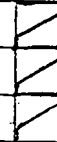
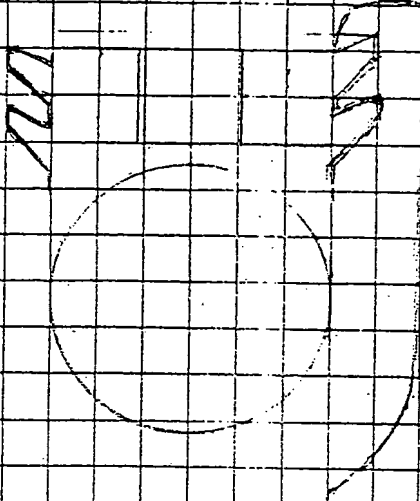
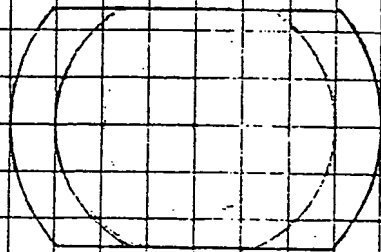
TERMS: NET 30 DAYS, 1½% SERVICE CHARGE PER MONTH AFTER 30 DAYS.
THIS IS AN ANNUAL PERCENTAGE OF 18%.

SEE REVERSE SIDE FOR ADDITIONAL TERMS & CONDITIONS.

PROJECT

Thread Design

Continued From Page



Continued on Page

Roger Jackson
Signed

3-31-99
Date

Read and Understood By

Chris Hall
Signed

5-7-99
Date

PROJECT Closure Mechanisms

Notebook No. _____

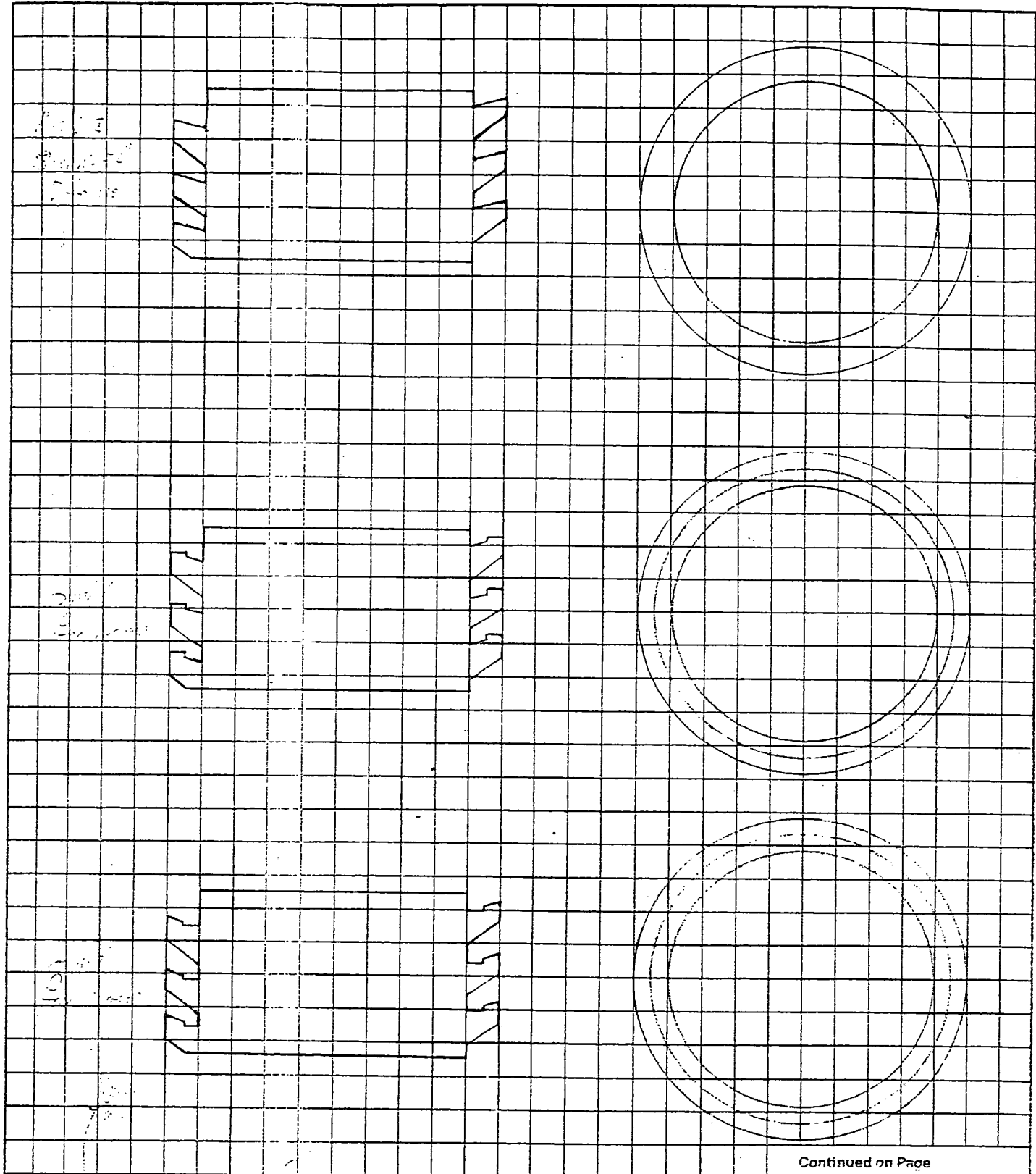
Continued From Page _____

Blumberg No. 5118

EXHIBIT

G

17



Continued on Page _____

Roger C. [Signature]
Signed

12-2-95
Date

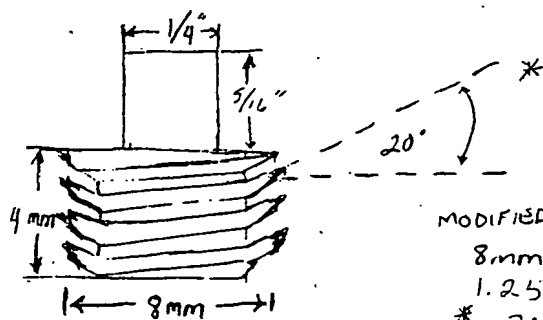
Read and Understood By

Chris Hah
Signed

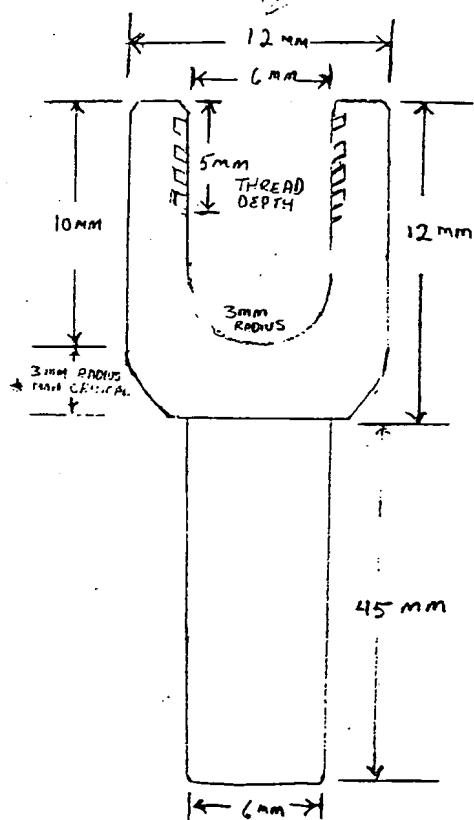
12-9-95
Date

Jackson Butress Thread

PART A (SET SCREW)



MODIFIED BUTRESS THREAD
 8mm MAJOR DIAMETER
 1.25 PITCH
 * 20° BACK RELIEF



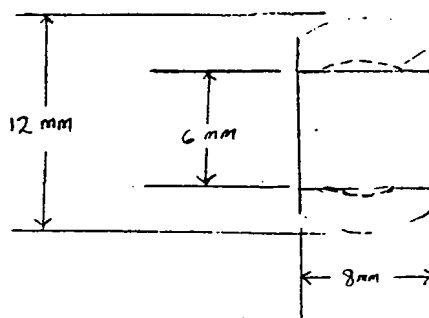
PART B (IMPLANT)

VIEW "A"

8mm INTERNAL
 1.25 PITCH
 JACKSON MODIFIED
 BUTRESS THREAD

PART B (IMPLANT)

VIEW "B" (TOP VIEW)



INTERNAL
 8mm
 1.25
 JACKSON MODIFIED
 BUTRESS

MATERIAL = TITANIUM

Action Stainless & Alloys, Inc.1505 Halsey Way, Carrollton, TX 75007
(972) 466-1500Please Remit Payment to: P.O. Box 890484
Dallas, TX 75389-0484

Blumberg No. 8118

EXHIBIT

I

INVOICE NO.	176314
PAGE	1
DATE	10/13/99

S
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O43500
JENKINS INDUSTRIAL MACH WORK
1137 SWIFT ST
N KANSAS CITY, MO 64116S
H
I
P
T
OJENKINS INDUSTRIAL MACH WORK
1137 SWIFT ST
N KANSAS CITY, MO 64116

CUSTOMER P.O. NO.	SHIP DATE	SLSP.	TERMS	TAX CODE	DOC. NO.	W/H	SHIP VIA
27776 <i>DoelKov</i>	10/13/99	41	NET 30 DAYS	N	6169824440		UPS PREPAID
ITEM	DESCRIPTION	ORDERED	SHIPPED	U/M	PRICE	PER	EXTENSION
3041.0	1" DIA TITANIUM 6AL-4V X long 1 pc *****PACKAGE WELL FOR SHIPMENT*****	1	1	EA	195.0000	EA	195.00
PAYMENT AND PERFORMANCE OF THIS AGREEMENT SHALL BE MADE TO OUR OFFICE IN DALLAS, TEXAS, DALLAS COUNTY.		MERCHANDISE	MISCELLANEOUS	TAX	FREIGHT	TOTAL DUE	
		195.00				243 ⁷⁵ 195.00	

Blumberg No. 5118

EXHIBIT

J





Bumbers No. 8118

EXHIBIT

L

U



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SUPPLEMENTAL DECLARATION UNDER RULE 131

Applicant: Roger P. Jackson

Serial No.: 09/644,777

Date: February 23, 2006

Filed: August 23, 2000

Group Art Unit: 3732

Exam: Candice Melson

For: THREADFORM FOR MEDICAL IMPLANT CLOSURE

Kansas City, Missouri

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant, Roger P. Jackson, inventor in the above application for patent avers and declares as follows:

- 1) The following is a supplement to my Declaration dated February 25, 2003 in the above captioned application in view of an earlier prototype that has been found which was not described in my earlier Declaration.
- 2) In the period of 1996 to 1997 and definitely prior to November 9, 1998, I had an implant closure (implant closure of Claim 1, closure implant of Claim 13,

closure of Claim 17, implant of Claim 18, closure of Claim 19, implant of Claim 21, closure of Claim 22, closure of Claim 26, closure of Claim 50 and closure of Claim 51) constructed in accordance with my instructions by Jenkins Industrial Machine Works in the United States.

- 3) The closure identified in Paragraph 2 had a cylindrical shaped body with a helically thread that was wound about the external cylindrical surface of the body. This closure was constructed of stainless steel. The thread was a reverse angle thread that had a trailing surface that was angled toward the top of the closure at approximately 1 to 2 degrees and definitely greater than zero degrees with respect to a radius of the body, such that in any horizontal cross section of the thread, both the leading and trailing surfaces of the thread sloped rearwardly relative to a horizontal plane perpendicular to the axis of rotation of the closure.
4. The later closures noted and described in Paragraph 10 of my Declaration of February 25, 2003 were constructed of titanium, whereas the closure described in the above paragraph was constructed of stainless steel.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,

Date: 2-22-06



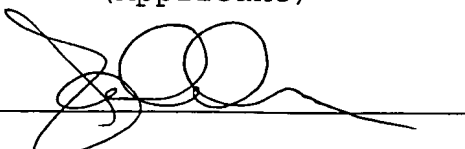
Roger P. Jackson, M.D.

JCM:lm
PO Box 30069
Kansas City, Missouri
64112
Phone: (816) 531-3470

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents,
P.O. Box 1450, Alexandria, VA 22313-1450
on February 23, 2006.

Roger P. Jackson
(Applicant)

By



February 23, 2006

(Date of Signature)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SUPPLEMENTAL DECLARATION UNDER RULE 131

Applicant: Roger P. Jackson

Serial No.: 09/644,777

Date: March 12, 2007

Filed: August 23, 2000

Group Art Unit: 3732

Exam: Candice Melson

For: THREADFORM FOR MEDICAL IMPLANT CLOSURE

Kansas City, Missouri

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant, Roger P. Jackson, inventor in the above captioned application for patent avers and declares as follows:

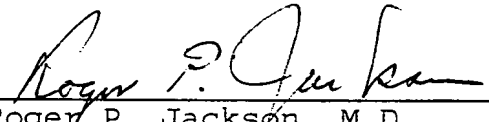
- 1) The present Supplemental Declaration is in addition to my Declaration dated February 25, 2003 and Supplemental Declaration dated October 12, 2006 in this application and is to be considered in conjunction with those earlier declarations.

- 2) As noted in the Declaration filed October 12, 2006, two stainless steel closures that were made for me by Jenkins Industrial Machine Works were found in a box of items made for me at Jenkins.
- 3) Enclosed herewith are photographs labeled Exhibits 1 to 5 showing one of the closures that was made for me at the latest during the Summer of 1997.
- 4) The closure shown in Exhibits 1 to 5 has a reverse angle thread thereon.
- 5) I had previously thought that the reverse angle on this closure was greater than one degree and probably in the two degree range; however, careful measurement of the reverse angle showed it to actually be 9.5 degrees relative to a radius perpendicular to the central axis of the closure, as is indicated in the photograph in Exhibit 4.
- 6) The closure shown in the photographs marked Exhibits 1 to 5 was constructed by the Jenkins machine shop located in North Kansas City, U.S.A., at my direction and in accordance with drawings and instructions provided by myself.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,

Date: 3-18-07



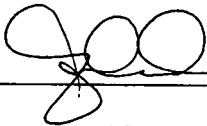
Roger P. Jackson, M.D.

JCM:lm
PO Box 30069
Kansas City, Missouri
64112
Phone: (816) 531-3470

I hereby certify that this
correspondence is being deposited
with the United States Postal
Service as first class mail in an
envelope addressed to:
Commissioner for Patents,
P.O. Box 1450, Alexandria,
VA 22313-1450 on April 16, 2007

Roger P. Jackson
(Applicant)

By

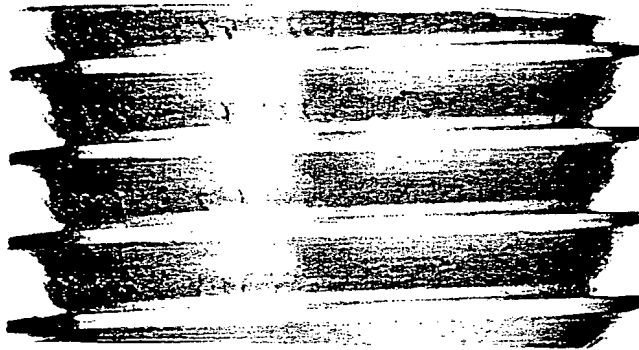


April 16, 2007

(Date of Signature)

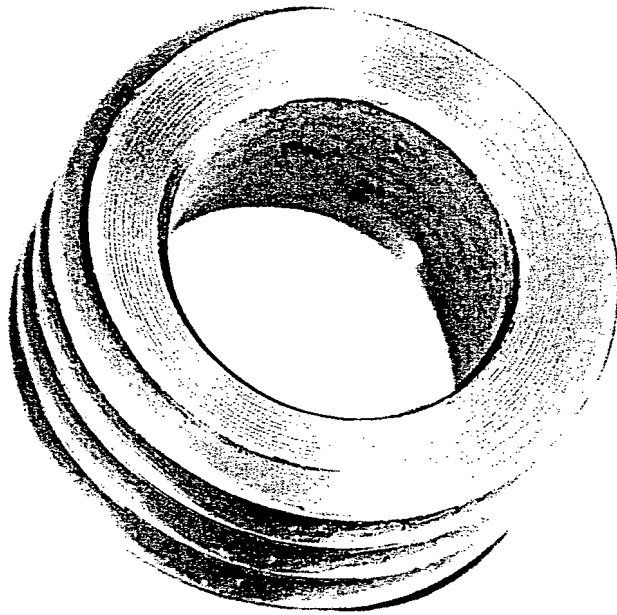
EXHIBIT

1



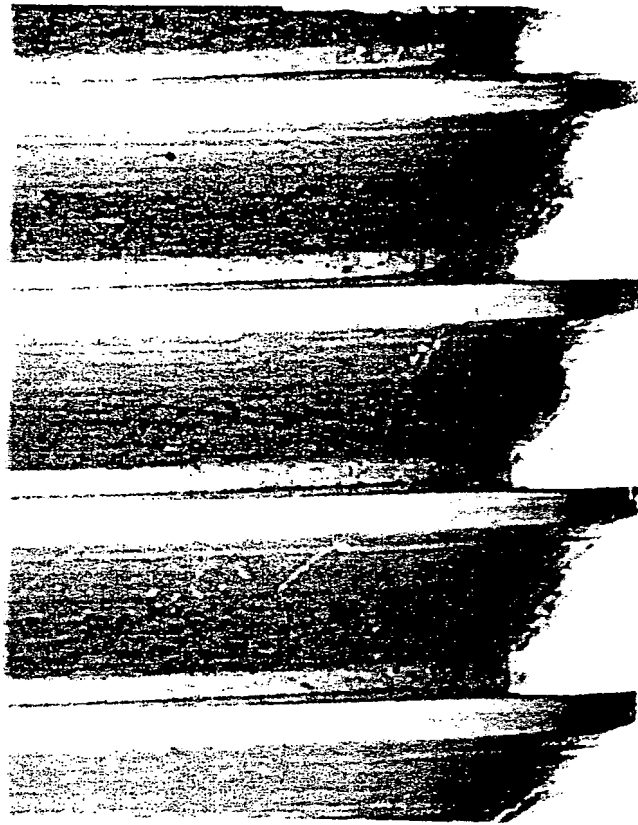
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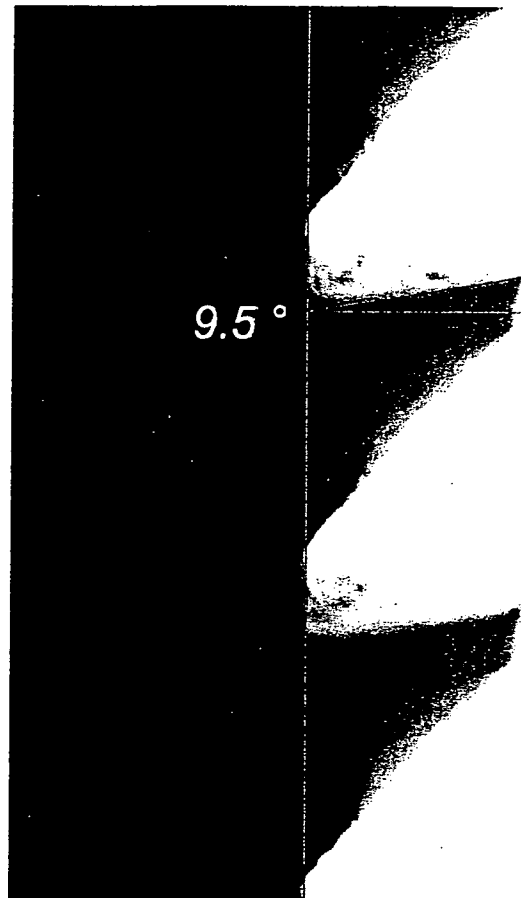
EXHIBIT

3



EXHIBIT

4



EXHIBIT

5

